

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 24 1998

Tracy A. Rood
Research and Product Approval Manager
Pioneer Hi-Bred International, Inc.
7100 NW 62nd Avenue
P.O. Box 1000
Johnston, Iowa 50131

Dear Ms. Rood:

This letter is in regard to your genetically modified corn lines 676, 678, and 680, about which you initiated a consultation with the Agency in June of 1996. According to Pioneer, the new corn varieties have been rendered male sterile through the anther-specific expression of the DNA adenine methylase (*dam*) gene derived from *Escherichia coli*.

As part of bringing your consultation with FDA regarding these products to closure, you submitted a summary of your safety and nutritional assessment of the new corn varieties on April 15, 1998. These communications informed FDA of the steps taken by Pioneer to ensure that these products comply with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Pioneer has concluded that corn grain and forage derived from the new corn varieties are not materially different in composition, safety, or other relevant parameters from corn grain and forage currently on the market, and that they do not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0036 and that will be maintained in the Office of Premarket Approval.

Based on the information Pioneer has presented to FDA, we have no further questions concerning corn containing transformation events TC676, TC678, and TC680 at this time. However, as you are aware, it is Pioneer's continued responsibility to ensure that foods, including corn forage, the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/S/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-246 HFS-247 HFS-13 HFV-200 **BNF 0036**